The FTC’s New Take on Health-Related Advertising: What Companies Facing FTC Enforcement Need to Know

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For at least the past decade, the vast majority of Federal Trade Commission (FTC or Commission) orders on health-related advertising have provided similar injunctive relief on future advertising claims. Specifically, most past orders simply have re-stated applicable law and required that companies possess “competent and reliable scientific evidence.” The FTC has defined competent and reliable scientific evidence broadly and flexibly as “tests, analyses, research or studies that have been conducted and evaluated in an objective manner by qualified persons and are generally accepted in the profession to yield accurate and reliable results.”

However, last year, in FTC v. LaneLabs, a New Jersey federal court dealt a blow to the FTC and held that a dietary supplement company was not liable for violating a previous order requiring competent and reliable scientific evidence. This loss – a rarity for the FTC – triggered a swift and decisive response. Soon thereafter, at conferences and in interviews, FTC staff announced that the Commission would revise its standard order...
language and substantiation guidance to be more specific. By July of this year, the FTC remained true to its word and announced two consent orders containing similar, more specific substantiation provisions. These provisions were almost immediately challenged as POM Wonderful, LLC filed a complaint in federal court on September 13, 2010, seeking declaratory standards are invalid, exceed the FTC’s relief and alleging that the substantiation LLC filed a complaint in federal court on immediately challenged as POM Wonderful, LLC filed a complaint in federal court on September 13, 2010, seeking declaratory standards are invalid, exceed the FTC’s relief and alleging that the substantiation

6 In sharp contrast to the broad, traditional competent and reliable scientific evidence standard, the orders require as follows:

- Weight loss claims (at issue in one case) and claims to treat diarrhea in children or prevent absences from school (at issue in the other case), must be substantiated by at least two “randomized, double-blind, placebo-controlled” clinical trials, conducted by “different researchers, independently of each other;” and

- Claims to treat or prevent disease (other than claims to treat diarrhea in children) must be approved under the Food and Drug Administration’s (FDA) drug approval process or allowed by an FDA monograph.

It remains to be seen whether such order provisions will become the de facto standard for substantiating certain types of health-related claims. Against this background, this article reviews (1) important precedent and policy considerations in favor of the prior, broad standard and (2) significant precedent that places limits on the FTC requiring more specific substantiation, as part of fencing-in relief.

The Competent and Reliable Scientific Evidence Standard

The traditional competent and reliable evidence standard was developed in the landmark case, Pfizer, Inc., following an attempt by FTC staff to establish “adequate and well-controlled studies” as the only “reasonable basis” for substantiating certain drug claims. The Commission rejected the proposed requirement that adequate substantiation always requires testing and held that a “reasonable basis” for a claim could include not only studies, but also medical literature, common usage and other standards supported by science. In finding that “complaint counsel . . . failed to demonstrate that the only reasonable basis for [certain] . . . affirmative product claims would be adequate and well-controlled scientific studies or tests,” the Commission rejected the argument that a “reasonable basis could [never] be found in medical literature, clinical experience, or general medical knowledge.” The Commission also noted that a rigid, inflexible substantiation standard would be inappropriate because there may be instances where scientific literature alone could provide the basis for a judgment of efficacy.

Since Pfizer, the FTC has focused the definition of competent and reliable scientific evidence on standards “generally accepted in the profession,” and with only a handful of exceptions has refrained from specifying rigid substantiation standards incapable of adaptation to changes in science over time. In fact, prior to Lane Labs, the FTC considered and consistently rejected broad proposals to impose more rigid standards. For example:

- In a 1983 Request for Comment on the Advertising Substantiation Program, the FTC specifically requested comment on whether it should issue general standards for advertisers under order or “specific standards (e.g., two well-controlled clinical studies).””12 The FTC’s final rule consciously declined to establish a specific standard of two well-controlled clinical studies.

- In 1998, after seeking input from stakeholders, the FTC published guidance on substantiating dietary supplement advertising. That guidance rejected “fix[ed] formulas” for the amount and type of substantiation and, instead, adopted the traditional, flexible competent and reliable scientific evidence standard.

- In 2000, the FTC denied a petition requesting rulemaking on dietary supplement claims substantiation and again declined to set specific standards: “[The Commission] has not established particular requirements for size, duration or protocol of scientific studies, nor has it provided any single fixed formula for the number and type of studies required to substantiate a claim. Instead, the Commission’s substantiation doctrine allows for some flexibility in the type and amount of evidence required depending on the nature of the claim and how it is presented and qualified. The Commission has determined that further refinement of the standard through rulemaking might result in a more rigid standard that, in some instances, could be higher than necessary to ensure adequate scientific support for certain specific claims.”

In cases where the FTC seeks to impose a substantiation requirement more specific than the traditional competent and reliable scientific evidence standard, companies should urge the FTC to consider the evolving nature of science. Pfizer’s endorsement of “medical literature, clinical experience, or general medical knowledge” as potential substantiation for claims and whether, over the time period during which the order is
imposed, the FTC's proposed standard could become "higher than necessary to ensure adequate scientific support for certain specific claims."

**Limits on FTC Fencing-In Relief**

The more specific provisions that the FTC is currently seeking constitute "fencing-in" relief. Fencing-in provisions reach more than the exact types of violations that were at issue in the investigation and are intended to prevent related deceptive acts or practices. The FTC has discretion in crafting orders and fencing-in relief, and courts will defer a great deal to the FTC's expertise before modifying an order. “Because of the Commission's expertise in determining what remedy is required to eliminate an unfair or deceptive practice, the Commission is granted wide latitude in deciding the scope of its orders. In drafting the FTC Act, Congress recognized that 'there is no limit to human inventiveness in [the advertising] field.' Accordingly, it authorized the Commission to draft orders encompassing, for instance, all of an advertiser's products or all products in a broad product category in order to 'fence in' known violators of the Act. 'Fencing-in provisions serve to "close all roads to the prohibited goal, so that [an] order may not be by-passed with impunity."' In reviewing the Commission's order, we must bear in mind its broad powers and its expertise in protecting consumers...”

Limits still exist, however, to the types of fencing-in provisions that the FTC may require.

**Order Provisions Must Be "Reasonably Related to Violations"**

Fencing-in provisions must bear a "reasonable relation" to the advertiser's violations of the FTC Act (FTC Act). In determining whether a reasonable relation exists, courts consider an array of factors. However, the baseline factor for consideration is whether the proposed relief is logically and rationally related to a defendant's violations.

In the landmark case, *FTC v. Colgate-Palmolive Co.*, the FTC challenged commercials representing that Colgate's product, Rapid Shave, had such "super-moisturizing power" that it allowed the sand to be shaved off of sandpaper immediately after application. In actuality, shaving sandpaper clean required a soaking time of about 80 minutes, and despite initial testing with real sandpaper, sand applied to plexi-glass was used in the ads. The Supreme Court upheld a fencing-in provision that prohibited misleading "test[s], experiment[s], or demonstration[s]" in ads, given that the provision had a "reasonable relation to the unlawful practices found to exist."

In contrast, in *Trans World Accounts, Inc. v. FTC*, the Ninth Circuit struck down a fencing-in provision lacking a reasonable relation to violations. The FTC sought to include in an order a provision barring a collection agency from misrepresenting the likelihood of legal action following failure to pay; however, the court found that such a provision was unwarranted, given that the defendant's violations related only to misrepresentations about the timing and immediacy of legal action.

In addition to the baseline requirement for a logical relationship, courts routinely consider the following factors in determining whether the breadth of fencing-in relief is "reasonably related" to the alleged violations:

- The deliberateness of the alleged violations;
- The seriousness of the alleged violations;
- The violator's past record with respect to advertising practices; and
- "[T]he adaptability or transferability of the alleged unfair practice to other products."

Other factors courts occasionally consider include the following:

- "[T]he seriousness of potential violations, including health hazards;"
- "[T]he difficulty for the average consumer to evaluate [advertising claims] through personal experience;" and
- Whether a provision is burdensome or oppressive.

"In analyzing [the] factors, no single factor is determinative; the 'more egregious the facts with respect to a particular element, the less important it is that another negative factor be present..." Courts... consider the circumstances of the violation as a whole, and not merely the presence or absence of any one factor."

Given the requirement for a "reasonable relation" between provisions and violations, a company faced with new, more specific forms of fencing-in relief should consider, first and foremost, the logical fit between the proposed relief and alleged violations. Importantly, as stated previously, the FTC's past orders on health-related claims simply have required competent and reliable scientific evidence for future claims. For those orders, the reasonable relationship between the violations and the remedy was obvious. However, for the more specific types of fencing-in recently proposed by the FTC, a reasonable relation is likely to be less clear. For instance, if the FTC seeks a requirement for testing by different, independent researchers, the affected company should demand evidence that researcher or institutional bias rendered the claims at issue deceptive.

Similarly, if the FTC seeks a requirement for specific test designs, the affected company should demand evidence that a lack of testing, using the same design, led to...
claims being deceptive. Companies, next, should consider carefully whether factors, such as the deliberateness and seriousness of the alleged violations, actually justify the proposed provisions, and whether any proposed provisions, in general, are overly burdensome or oppressive in light of the alleged violations.

Order Provisions Must Comply with First Amendment Standards

Closely related to the requirement for a “reasonable relation” between provisions and violations, a company faced with more specific forms of fencing-in also should consider the First Amendment implications. “The First Amendment does not permit a remedy broader than that which is necessary to prevent deception, or correct the effects of past deception.” In Litton Industries, Inc. v. FTC, the FTC found that sellers of microwave ovens had deceived consumers by advertising the results of a flawed survey. The Ninth Circuit upheld provisions of an FTC order that prevented misrepresentation of future surveys, but struck down provisions on misrepresenting “tests,” other than surveys. Unlike the survey provisions, the test provisions were “not reasonably necessary to the prevention of future violations.”

Similarly, in Nat’l Comm’n on Egg Nutrition v. FTC, the FTC found that a trade group for the egg industry had deceptively advertised that no scientific evidence existed to show that eggs increase the risk of heart disease. The Seventh Circuit upheld an FTC order, insofar as it prevented similar misrepresentations in the future. The court, however, modified a provision that would have required the trade group to include in all ads a statement “that many medical experts believe increased consumption of dietary cholesterol, including that in eggs, may increase the risk of heart disease.” The court reasoned as follows: “The First Amendment does not permit a remedy broader than that which is necessary to prevent deception or correct the effects of past deception. . . . The condition in its present form would require [the trade group] to argue the other side of the controversy, thus interfering unnecessarily with the effective presentation of the pro-egg presentation. The desired preventive effect can be achieved by requiring the disclosure that there is a controversy among the experts and [the trade group] is presenting its side of that controversy. The additional statement in the form now ordered by the FTC should be required only when [the trade group] chooses to make a representation as to the state of available evidence or information concerning the controversy. As thus modified, the challenged condition would not unnecessarily curtail [the trade group’s] right to present its position.”

Like the tests provision in Litton and the disclosure provisions in Nat’l Comm’n on Egg Nutrition, new, more specific fencing-in provisions on health-related advertising must not be broader than necessary to prevent deception or correct past deception. Alongside these cases, which focus strictly on fencing-in, Pearson v. Shalala and its progeny are also useful to consider. The Pearson cases involved FDA regulation of dietary supplement labeling claims, but nevertheless reached helpful broader conclusions on the limits the First Amendment places on the regulation of health-related commercial speech. The thrust of the cases is that when “credible evidence” supports a claim . . . the claim may not be absolutely prohibited.” Thus, in the context of fencing-in, before strictly prescribing substantiation standards (e.g., at least two “randomized, double, blind, placebo-controlled” clinical trials by different, independent researchers), the FTC must establish that no other evidence could be considered “credible” and that requiring disclosures on any lesser type of evidence would not be adequate to prevent or correct deception.

Conclusion

In any FTC investigation of health-related advertising, a variety of precedents may come into play. For instance, a case involving a challenge to claims by a doctor and its progeny are

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3 Civ. No. 00-cv-3174, slip op (D.N.J. Aug. 11, 2009).

4 See, e.g., Dan Schiff, FTC Sharpens Consent Order Language in the Wake of LaneLabs, The Tan Sheet, Nov. 16, 2009, at 18.


8 See 81 F.T.C. 23 (1972), at 65.

9 Id.

10 Id. (noting that the guidelines for National Academy of Science National Research Council (“NAS-NRC”) panels utilized by FDA permitted judgments to be based on “(1) factual information that is freely available in scientific literature, (2) factual information that is available from FDA, from the manufacturer or other sources, or (3) on the experience and informed judgment of the members of the Panel(s)”). The Commission also noted that the NAS-NRC guidelines stated: “it is anticipated that substantial evidence from the effectiveness of many . . . [products], assigned to a Panel will be found to be well-documented in the scientific literature familiar to the members of the panel . . . [and] [i]n these cases, the Panel may be prepared to make its recommendations and to support them by citations from the scientific literature alone . . . “

11 Id. The guidelines for NAS-NRC panels also acknowledged “wide usage” as a “special consideration” that can be used to substantiate a claim regarding the efficacy of a product. Id. at 70. Similarly, in 1997, Congress enacted the Food and Drug Administration Modernization Act, which established an alternative authorization procedure for health claims based on authoritative statements of certain federal scientific bodies or the National Academy of Sciences. See Federal Food, Drug, and Cosmetic Act section 403(r) (3)(C) (21 U.S.C. § 343(s)(3)(C)).

12 See cases cited supra note 1.


17 Most FTC orders are imposed for a minimum of twenty years.

18 See, e.g., Direct Mkts., 884 F.2d at 1499-1500 (internal citations omitted).

19 See Sterling Drug, 741 F.2d at 1156; Standard Oil, 570 F.2d at 660-663; Sears, Roebuck & Co. v. FTC, 676 F.2d 385, 394-396 (9th Cir. 1982). This factor has not been named among the list of factors, but has strong resonance; it may have been the dispositive factor in Standard Oil.

20 Removatron Int’l Corp., 884 F.2d at 1499-1500 (internal citations omitted).


22 570 F.2d 157, 164 (7th Cir. 1978) (internal citations omitted); see also, e.g., Direct Mkts. Concepts, 648 F. Supp. 2d at 213 (“Permanent injunctions, however, must not infringe the defendants’ First Amendment rights”).

23 See 767 F.2d at 367-68.

24 See id. at 371-372.

25 See id. at 373-374.

26 See id. at 375.

27 See 570 F.2d at 158-159.

28 See id. at 164.

29 Id.


31 See Pearson II, 130 F. Supp. 2d at 114.